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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/724,427

11/28/2000

Peter Palese

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20583

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04/28/2006

JONES DAY

222 EAST 41ST ST

NEW YORK, NY 10017

EXAMINER

GARVEY, TARA L

ART UNIT

PAPER NUMBER

1636

DATE MAILED: 04/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/724,427

Applicant(s)

PALESE ET AL.

Examiner

Tara L. Garvey

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 February 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 35-56 is/are pending in the application.
- 4a) Of the above claim(s) 41-46 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 56 is/are allowed.
- 6) ☒ Claim(s) 35-40 and 47-55 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Claims 1-56 are pending. Receipt of an amendment filed on February 3, 2006 is acknowledged in which claims 41-46 are withdrawn, claims 35, 36, 37, 47, 48 and 50 are amended and claim 56 is added.

Priority

Receipt of an amendment to the specification in which the claim to priority in the first paragraph of the specification was corrected is acknowledged.

Oath/Declaration

The receipt of a courtesy copy of the oath filed in the parent application 08/252,598 is acknowledged.

Claim Objections

The objection of claims 35-40, 47 and 51-55 is withdrawn in view of applicant's amendment.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 47-52 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which

applicant regards as the invention for reasons of record as set forth in the office action mailed on June 28, 2005.

Applicant's argue that the rejection should be withdrawn in view of the amendment to claims 47, 48 and 50 in which "of" has been changed "comprising." Thus, they argue that now the claims recite a method step in addition to a preamble.

In response to applicant's arguments, the claims still do not contain any active method steps and merely describe the structure of the DNA molecule. Thus, it is unclear what steps are encompassed to result in the construction of a DNA molecule as claimed.

Claims 47-52 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for reasons of record as set forth in the office action mailed on June 28, 2005 and above.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 47-52 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claims are drawn to methods that lack any method steps and thus are not actual methods. Because these claims are not actual methods or any other statutory subject matter, the instant claims are directed to non-statutory subject matter.

Applicant's argue that the rejection should be withdrawn in view of the amendment to claims 47, 48 and 50 in which "of" has been changed "comprising."

In response to applicant's arguments, the claims still do not contain any active method steps and therefore are not directed to non-statutory subject matter.

Claims 47-52 stand rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter for reasons of record as set forth in the office action mailed on June 28, 2005 and above.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claim 35 is rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 27 of prior U.S. Patent No. 5,166,057 (Applicant reference 130) for reasons of record as set forth in the office action mailed on June 28, 2005. This is a double patenting rejection.

Applicant's argue that there is nothing in the language of the claim or in the specification that directly states or suggest that the RNA sequence must be

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heterologous. Since the RNA does not have to be heterologous, the statutory doubling patenting rejection should be withdrawn.

In response to applicant's arguments, the nature of the invention lends the RNA sequence to being heterologous since it is contained in a recombinant molecule and since a "reverse complement of an mRNA coding sequence of a negative strand RNA virus" is not a naturally occurring sequence.

Claim 35 stands rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 27 of prior U.S. Patent No. 5,166,057 (Applicant reference 130) for reasons of record as set forth in the office action mailed on June 28, 2005 and above.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 35-40 and 53-55 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 8, and 27-29 of U.S. Patent No. 5,166,057 (Applicant reference 130) for reasons of record as set forth in the office action mailed on June 28, 2005.

Applicant submits that filing a terminal disclaimer over U.S. patent 5,166, 057 will obviate the rejection based on obviousness-type double patenting.

In response to applicant's argument, the terminal disclaimer has not yet been filed; therefore, the claims are still rejected based on obviousness-type double patenting.

Claims 35-40 and 53-55 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 8, and 27-29 of U.S. Patent No. 5,166,057 (Applicant reference 130) for reasons of record as set forth in the office action mailed on June 28, 2005 and above.

Allowable Subject Matter

Claim 56 is allowed.

Conclusion

Claims 35-40 and 47-55 are rejected. Claim 56 is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) (<http://pair-direct.uspto.gov>) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history

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information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Tara L Garvey, Ph.D.
Examiner
Art Unit 1636

TLG

CELINE QIAN, PH.D.
PRIMARY EXAMINER

A handwritten signature in black ink, appearing to be 'C. Qian', written in a cursive style.